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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,271	08/05/2008	Andrew John Ede	IPLTP0106US	8739

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EXAMINER	
VASAT, PETER S	

ART UNIT	PAPER NUMBER
3764	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,271	EDE ET AL.	
	Examiner	Art Unit	
	PETER S. VASAT	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites that the “moisture-proof barrier… …encloses the dose-storage region of the inhaler without enclosing the doses individually." This limitation is indistinct because it is unclear from the language of the claim how the moisture-proof barrier could ever enclose the dose-storage region without also enclosing the doses individually. One of ordinary skill could conclude that it would be impossible for the barrier to enclose the dose-storage region without also enclosing the individual doses contained within the dose-storage region. For the purposes of examination, the limitation was interpreted to mean that the individual doses were disposed within a dose-storage region and that the dose storage region was enclosed by a moisture-proof barrier.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stradella (US 6082356) in view of Howlett (US 6336455).

a. In re claims 1 and 2, Stradella discloses a non-reservoir, pre-dosing type, inhaler (col. 1, ll. 12-28). Stradella further discloses a moisture-proof barrier (hermetically sealed and genuinely kept separate from the atmosphere) that encloses the dose-storage region of the inhaler (col. 1, ll. 19-36). However, Stradella does not disclose that the moisture-proof barrier encloses the dose-storage region of the inhaler without enclosing the doses individually and that the inhaler includes a moisture-proof aperture through which the medicament doses can, in use, be individually dispensed. Howlett teaches an inhalation apparatus for dispensing medicinal products for inhalation (col. 1, ll. 4-6) by entrainment (col. 2, ll. 6). Howlett further teaches a pressurized container 30 that encloses medicament in a dose storage region (col. 2, ll. 54-61). Howlett further teaches a moisture-proof aperture 63 (valve stem) through which the medicament can be individually dispensed (col. 5-6, ll. 45-9; fig. 9). Howlett's container 30 must be pressurized at pressures greater than ambient pressure to allow dispensing of

the medicament. Since Howlett's container 30 and aperture 63 are pressurized in excess of ambient pressure, they would be moisture proof because the interior pressure of container 30 and aperture 63 are higher than the vapor pressure of water, which is equal to the ambient pressure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stradella with the moisture-proof container and aperture taught by Howlett to provide an inhalation apparatus for dispensing medicinal products for inhalation by entrainment.

b. In re claim 4, Stradella further discloses a dry powder inhaler (col. 1, ll. 12-28).

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stradella (US 6082356) in view of Howlett (US 6336455), and further in view of Miekka (US 6378518).

c. In re claim 3, Stradella in view of Howlett disclose the invention as discussed above in claim 2, but they do not explicitly disclose an inert gas used to raise the internal pressure to above atmospheric pressure. Miekka teaches a method for producing uniform small doses of finely divided substances and more particularly, relates to a technique employing nitrogen as a dispersing medium for the purpose of packaging fine medicaments (col. 1, ll. 1-11). Miekka further teaches that the method for repeatedly filling unit dose packages with accurate masses of fine powder medicament (col. 2, ll. 30-36). Miekka further teaches that it is preferable to maintain a positive pressure of an inert gas in the

medicament container in order to prevent degradation of extremely unstable substances (col. 4, ll. 45-62). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stradella in view of Howlett with inert gas at a positive pressure taught by Miekka to prevent degradation of extremely unstable substances.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stradella (US 6082356) in view of Howlett (US 6336455), and further in view of Bell (US 4161516).

d. In re claim 5, Stradella in view of Howlett disclose the invention as discussed above in claim 4, but they do not disclose that the dry powder is stored as an agglomeration or pellet, and the inhaler further comprises means for disrupting said pellet or agglomerate during its dose-dispensing cycle. Bell teaches dry powder pellets and means for disrupting the pellets (col. 1, ll. 1-42). Bell further teaches that the formation of medicaments into pellets aids the filling of the medicament into capsules and can reduce or eliminate the need for binders such as lactose (col. 1, ll. 37-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stradella in view of Howlett with the dry powder pellets and means for disrupting the pellets taught by Bell to reduce or eliminate the need for binders such as lactose.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stradella (US 6082356) in view of Howlett (US 6336455), and further in view of Arnow (US 2603215)).

e. In re claim 6, Stradella in view of Howlett disclose the invention as discussed above in claim 1, but they do not disclose that apparatus of claim 1 further comprises a scavenger – such as desiccant or an oxygen scavenger- in gaseous communication with the dose-storage region of the inhaler. Arnow teaches apparatus and methods for applying powdered medicament to various passages of the body (col. 1, ll. 1-8). Arnow further teaches that the apparatus is sturdy, dependable, reliable, and will maintain its characteristics for a long period so that if considerable time should elapse between the original manufacture of the item and its utilization, the therapeutic efficacy of the drug will remain undiminished (col. 1, ll. 22-29). Arnow further teaches a desiccant in gaseous communication with the dose-storage region of the inhaler (col. 2-3, ll. 49-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stradella in view of Howlett with the desiccant in gaseous communication with the dose-storage region of the inhaler taught by Arnow to provided a powder inhaler that is sturdy, dependable, reliable, and will maintain its characteristics for a long period so that if considerable time should elapse between the original manufacture of the item and its utilization, the therapeutic efficacy of the drug will remain undiminished.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stradella (US 6082356) in view of Howlett (US 6336455), and further in view of Ingle (PGPub 20010029948).

f. In re claim 7, Stradella in view of Howlett disclose the invention as discussed above in claim 2. Stradella further discloses placing a desired number of individual doses of powdered medicament into the inhaler (col. 5, ll. 54-56). Also, as discussed above in claim 2, Howlett discloses sealing the container in a manner which will resist depressurization whilst allowing individual dose dispensation via the moisture-proof aperture 63 (col. 5-6, ll. 45-9). Howlett's moisture-proof aperture 63 allows the container to resist depressurization because it dispenses metered doses to an airlock ("first chamber"; col. 5, ll. 34-44), rather than being freely open to the atmosphere. However, Stradella in view of Howlett do not disclose raising the pressure of the dose-storage region of the inhaler internally to above atmospheric pressure. Ingle teaches methods for extracting powdered medicaments from receptacles during the aerosolizing process (par. 2) that advantageously reduce the amount of material remaining within the cavity and produce a low average particle size, which indicates successful deagglomeration (par. 23). Ingle further teaches a method of raising the pressure of the dose-storage region of the inhaler internally to above atmospheric pressure (claim 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stradella in view of Howlett with the method of raising the pressure of the dose-storage region of the inhaler internally to above atmospheric pressure taught by Ingle to provide a powder inhaler that advantageously reduce the amount of material remaining

within the cavity and produce a low average particle size, which indicates successful deagglomeration.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Issler (PGPub 20020172566), Rose (US 5687746), Abplanalp (US 3425600), Hodson (US 5655523), and Quaas (US 3228610) all relate to dispensing powders using various means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER S. VASAT whose telephone number is (571)270-7625. The examiner can normally be reached on Monday - Thursday, 8:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571)272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PETER S. VASAT/
Examiner, Art Unit 3764

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764